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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,143	12/31/2003	Maurice Bhague	069208.0115	7930
23640	7590	02/19/2010		
Baker Botts L.L.P. 910 Louisiana Street, One Shell Plaza HOUSTON, TX 77002				
EXAMINER				
HAND, MELANIE JO				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
02/19/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/750,143

Applicant(s)

BEHAGUE ET AL.

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 5, 2009 have been fully considered but they are not persuasive. AS to the argument that Truitt does not disclose collecting a biological fluid by natural flow, Col. 3, lines 54-57 of Truitt make it clear that blood is fed to the apparatus directly from an arterial or venous catheter, i.e. no pump is present. Pump 52 feeds collected blood to the primary circuit and is not relevant to the method step of collecting a biological fluid in the Truitt apparatus. As to the argument that Truitt does not disclose measuring a natural fluid flow rate of the biological fluid, Truitt discloses measuring fluid flow rate via scales 92. Scales 92 measure fluid in collection container 86 which is collected when blood passes through a semi-permeable member. There is no pump at this point in the process either, therefore the flow rate is necessarily a natural flow rate. AS to the argument that Truitt does not disclose adjusting the fluid flow rate to preserve a selected ratio between collected fluid and anticoagulant/preservation solution, applicant is referred once again to Col. 6, lines 33-50, which does not just discuss a single computer as applicant asserts. The passage clearly states that the computer 102 responds to signals from the scales, which weigh respective amounts of fluid and anticoagulant. Truitt then states in Col. 7, lines 1-4 that control signals from the computer 102 are delivered over the control signal path to control the operation of pumps 52, 62, 66, 78 and 84. This process of receiving monitor signals and executing control signals to control the operation of the pumps is necessarily a disclosure of a step of adjusting the fluid flow rate to preserve a selected ratio between the collected fluid and the anticoagulant. As to arguments regarding the rejections of certain claims under 35 U.S.C. 103, O'Riordan does not need to

meet the limitation of collecting biological fluid by natural flow; this limitation is already met by Truitt.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Truitt et al (U.S. Patent No. 5,910,252).

With respect to **claim 1**: Truitt discloses a method of collecting a biological fluid comprising the following steps: collecting a biological fluid, namely blood, by natural flow without a pump (Col. 3, lines 54-57); measuring a fluid flow rate of the biological fluid via scales 92 (Col. 6, lines 10,11); pumping preservation solution in the form of replacement fluid from a reservoir 68 via third pump 66 to the collected biological fluid, necessarily at a solution flow rate (Col. 5, lines 29-31); wherein measuring a fluid flow rate of the biological fluid comprises weighing the collected fluid via scales 92, the pumped preservation solution (already in the collected fluid container) and any preservation solution remaining in the reservoir via scale 72 and the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected fluid and the preservation solution. (Col. 6, lines 33-50)

With respect to **claim 2**: The method disclosed by Truitt further comprises collecting the blood/biological fluid in a collection bag 86 (Col. 5, line 61 – Col. 6, line 3); pumping the preservation solution to the bag 86 via primary circuit 38 and primary chamber 44 (Col. 5, lines 31-37, Col. 5, line 67 – Col. 6, line 3), wherein the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected fluid and the preservation solution. (Col. 6, lines 33-50)

With respect to **claim 3**: The biological fluid disclosed by Truitt comprises blood. (Abstract)

With respect to **claim 4**: Truitt discloses measuring actual flow rate of the collected fluid via scales 92, and the flow rate and weight of preservation solution remaining in bag 68 via scale 72 but does not explicitly disclose calculating a variation in weight of the collected fluid, the pumped preservation solution and any preservation solution remaining in reservoir 68. However one of ordinary skill in the art could readily and easily perform this step by observing the readout on scales 72 and 92 and either mentally determining the difference in weight or by using a mathematical aid. Therefore it would be obvious to one of ordinary skill in the art to modify the method of Truitt such that the step of measuring a fluid flow rate of the biological fluid further comprises calculating a variation in weight of the collected fluid, pumped preservation solution (already in the collected fluid) and any preservation solution remaining in the reservoir with a reasonable expectation of success to properly discern whether or how much preservation solution is needed or desired.

With respect to **claim 18**: Truitt discloses collecting the biological fluid with a collection device, namely catheter 33, in fluid communication with the collection bag 86 via a tube in the form of

collection line 82 and detecting the presence of the biological fluid in the tube via leak detector 85. (Col. 6, lines 12-15)

With respect to **claim 19**: Truitt discloses that detecting the presence of the biological fluid, blood, in the tube 82 by leak detector 85 comprises optical sensing. (Col. 6, lines 12-15)

With respect to **claim 20**: The method of Truitt further discloses collecting a sample of the biological fluid by natural flow without a pump. (Col. 3, lines 54-57)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Truitt et al (252) in view of O'Riordan (EP 583,148 A2).

With respect to **claim 5**: Truitt discloses that the step of pumping comprises using a pump having a variable rotation speed inasmuch as the output of the pump is altered by control signals. ('252, Col. 6, lines 35-44) However, Truitt does not explicitly disclose that the step of pumping comprises using a peristaltic pump having a variable rotation speed. The method taught by O'Riordan comprises a step of pumping anticoagulant, wherein the act of pumping comprises pumping using a peristaltic pump 42 having a variable rotation speed, inasmuch as the minimum pump speed can be set and the operation of the pump is controlled to ensure maintenance of the desired flow rate of anticoagulant. ('148, Page 3, lines 54, 55; Page 5, lines 4,5) Since the prior art of O'Riordan seeks to solve a similar problem in the art to that with which applicant is concerned it would be obvious to one of ordinary skill in the art to modify the method of Truitt such that the step of pumping comprises using a peristaltic pump having a variable rotation speed as disclosed by O'Riordan with a reasonable expectation of success to allow changes in blood or preservation solution flow rate to ensure proper physiological balance for the patient.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761